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| APPLICATION NO./ | FILING DATE | FIRST NAMED INVENTOR / | | ATTORNEY DOCKET NO. | |
|--|------------------|-------------------------|----------------|---------------------|--|
| CONTROL NO. | | PATENT IN REEXAMINATION | | | |
| 10/613,590 | 6/30/03 | SZYNALSKI | Goens Seminars | | |
| PHARMACEUTICAL PA | ATENT ATTORNEYS, | EXAMINER | | | |
| 55 MADISON AVENUE 4 TH FLOOR | | ACKUN | | | |
| MORRISTOWN, NJ 079 | 60-7397 | | ART UNIT | PAPER | |

3723

DATE MAILED: 11/15/04

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | Application I | No. | Applicant(s) | | | | |
|--|--|--|--|--|-----------------------|--|--|--|
| Office Action Summary | | 10/613,590 | 10/613,590 90/006704 SZYNALSKI, ALEXAN | | EXANDER GOEN | | | |
| | | Examiner | | Art Unit | | | | |
| | | Jacob K. Ack | | 3723 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | | |
| A SH THE - Exte after - If the - If NO - Failu Any | ORTENED STATUTORY PERIOD FOR RE MAILING DATE OF THIS COMMUNICATIO nsions of time may be available under the provisions of 37 CFF SIX (6) MONTHS from the mailing date of this communication. a period for reply specified above is less than thirty (30) days, a period for reply is specified above, the maximum statutory per ure to reply within the set or extended period for reply will, by stareply received by the Office later than three months after the med patent term adjustment. See 37 CFR 1.704(b). | N. R 1.136(a). In no event, he reply within the statutory find will apply and will expand the cause the application. | nowever, may a reply be time minimum of thirty (30) days bire SIX (6) MONTHS from on to become ABANDONE | nely filed s will be considered time the mailing date of this of 0 (35 U.S.C. § 133). | ly. communication. | | | |
| Status | | | | | | | | |
| 1) | Responsive to communication(s) filed on | | | | | | | |
| 2a)□ | | his action is non- | final. | | | | | |
| 3)□ | | | | | | | | |
| Dispositi | ion of Claims | , | | | | | | |
| 5)□ 6)⊠ 7)□ | 4) ☐ Claim(s) 1-53 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-53 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement. | | | | | | | |
| Applicati | ion Papers | | | | | | | |
| 10) | The specification is objected to by the Exame The drawing(s) filed on is/are: a) and a Applicant may not request that any objection to the Replacement drawing sheet(s) including the continuous the oath or declaration is objected to by the | accepted or b) () on the drawing(s) be here tection is required if | eld in abeyance. See the drawing(s) is obj | 37 CFR 1.85(a). ected to. See 37 CI | | | | |
| Priority u | ınder 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| 2) Notic 3) Infor | t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/r No(s)/Mail Date | 08) 5) | Interview Summary (Paper No(s)/Mail Dat Notice of Informal Pa Other: | te |)-152) | | | |

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- 1. In accordance with the Decision of 12/10/03 merging applications 10/613,590 and 90/006,704, the examiner has issued the same office action in each case although the reissue application contains 53 claims and the re-examination has 8 claims. The 8 claims of the re-examination are the same as the first eight claims of the reissue at this time.
- 2. In view of the number of documents attached as part of the IDS submitted by applicant, the applicant is kindly requested to complete the name of the patentee and date of the patent for each patent listed on the attachments to the IDS and to resubmit these attachments with applicant's response to the instant office action. This information is required for the relevant documents to be printed on the first page of any patent to mature from the instant application. The applicant should also complete the fields including Application Number, Group Art Unit, etc., in the top right corner of each attachment to the IDS listing documents to be considered. These actions will also facilitate the mailing to applicant of initialed copies of the listings pursuant to the Rules no later than the next office action.
- 3. This application is objected to under 37 CFR 1.172(a) as the assignee has not established its ownership interest in the patent for which reissue is being requested. An assignee must establish its ownership interest in order to support the consent to a reissue application required by 37 CFR 1.172(a). The assignee's ownership interest is established by:
- (a) filing in the reissue application evidence of a chain of title from the original owner to the assignee, or
- (b) specifying in the record of the reissue application where such evidence is recorded in the Office (e.g., reel and frame number, etc.).

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The submission with respect to (a) and (b) to establish ownership must be signed by a party authorized to act on behalf of the assignee. See MPEP § 1410.01.

An appropriate paper satisfying the requirements of 37 CFR 3.73 must be submitted in reply to this Office action. NOTE THE REQUIREMENT FOR REEL AND FRAME NO. AS INDICATED ABOVE.

4. Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 6,431,874 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

- 5. The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.
- 6. In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) may be necessary depending on the nature of any claim amendments applicant may make in response to this office action, and such oath/declaration must be received before this reissue application can be allowed.

An example of acceptable language to be used in the supplemental oath/declaration is as follows:

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"Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

A Protest in the reissue application was filed on 11/13/2003. In accordance with MPEP 7. 1901.06 the following is a statement of the examiner's consideration of the Protest. The Protest indicates that claims 1-8 in the reissue application (the same claims as in US Patent No. 6.431,874 hereinafter "the 874 patent", as corrected by a Certificate of Correction of 11/18/03), are anticipated under Section 102 or obvious under Section 103 of the Statute in view of the prior art Gary Method public uses, public sales, offers for sale and publications documented in the Shira Block Declaration in conjunction with patent applicant's admission that Gary provided education and hypnosis. The examiner agrees that at least the independent claims herein are not patentable over the aforementioned materials hereinafter "Gary Method" (not to include the admission of patent applicant as set forth above). It is clear from the Gary Method alone that education and hypnosis, practiced together in the context of smoking cessation, is prior art. In summary the Gary Method appears to clearly show that it is conventional to practice the three elements of independent claims 1 and 3 together, namely education, hypnosis and lobelia. The Gary method also teaches the prerecorded media of dependent claims 2 and 4, at least based on the cassette tapes disclosed. Moreover the prior art of record appears to indicate that the provision of a weight control product as part of a stop smoking regimen, as set forth in claims 4-8, is also conventional.

The Protest also indicates that the '874 patent claims are not allowable over the information contained in an exhibit 5 apparently attached to the Protest and titled "Submission of Prior Art Under 37 CFR 1.501". The examiner can not locate such a document in the papers officially scanned into the reissue electronic file. However, the examiner has come across

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facsimile transmissions of two documents entitled "Submission of Prior Art Under 37

CFR1.501" in the reexamination file with which this reissue is combined. These documents were received on 08/12/2003 from Michael Comman and each includes four attachments: The Goen "Stop Smoking with Hypnosis in Just 2 Hours" advertisement 1995, Goen Seminars Stop Smoking Workbook 1995 or 1997, Gorayeb "Stop Smoking With Hypnosis in Just 2 Hours" advertisement 1995 and Gorayeb Seminars Stop Smoking Seminar Workbook 1996. (The two facsimile transmissions appear to differ only in that in one the 1997 Goen workbook was apparently erroneously submitted to the PTO instead of the 1995 workbook). The facsimile transmissions also indicate that copies thereof were submitted to applicant's representative.

Assuming that these documents are what exhibit 5 as indicated above refers to, the examiner further agrees with Protestor that claims 1-8 herein are not patentable over the noted materials. Both the Goen and Gorayeb workbooks appear to clearly teach education, hypnosis and an anti smoking drug. It is noted herein that consistent with the Protest the examiner considers both the Cal. Mag./B-Complex and theStop Smoking Lozenges taught in Gorayeb to be anti-smoking drugs or substances as those terms may be used in the '874 patent. However, it is further noted that with the changes made in the above noted Certificate of Correction, only the Goen workbook would be anticipatory since this is the only document out of the four that makes specific reference to lobelia. The Goen workbook (1995) and the Gary Method together with other references cited by the applicant or examiner form the basis of the grounds of rejection based on prior art which follow.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

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harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of copending Application No. 10/023,254. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious in view of the claims of the aforementioned application to provide the product and conduct the method recited in the instant application in order to facilitate effective smoking cessation.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

- 10. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 11. Claims 1-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1-53 are also rejected under 35 U.S.C. 112, first paragraph, as failing to

comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

First, a number of claims recite "lobelia in an amount effective to aid in the reduction or cessation of said tobacco smoker's craving to smoke tobacco", or a similar limitation. It is not clear from the specification what such an effective amount of lobelia, as claimed, might be. It is also not clear from a reading of the specification what substances might be encompassed by the claim expression "equivalent of lobelia". For example, the specification does not refer to an "equivalent of lobelia".

- The following is a quotation of the second paragraph of 35 U.S.C. 112: 12. The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- Claims 1-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for 13. failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what is encompassed be "an effective amount of lobelia as recited in the claims. With regard to new claims 9-53, they are indefinite because the scope of the phrase "equivalent of lobelia" can not be determined. Furthermore, in claims 3 and 11 the phrase "said educational program" lacks antecedent basis. Claim 31 is also indefinite because it recites all of the same substances as in claim 30 from which it depends, although claim 30 is limited to but one of the substances. Accordingly claim 31 would not appear to be properly dependent on claim 30.
- The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the 14. basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 15. Claims 1-5, 9-13, 15, 22, 23, 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by the Goen Workbook or the Gary Method. Either reference predates the claims in the instant application by at least one year. Each clearly teaches education, at least one hypnosis program and lobelia in an amount effective to aid in the reduction or cessation of craving for tobacco, as recited in all of the independent claims. Either reference also clearly teaches recorded media. Note that the Gary workbook by itself is considered to show the relevant limitations as well as the Gary workbook supported by the materials provided by Shira Block, comprising the aforementioned Gary Method.
- 16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 17. Claims 1-5, 9-13, 15, 22, 23, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Gary Method. This rejection is applied in the event it is later determined that the plurality of documents comprising the Gary Method be properly treated with respect to the claims at bar under section 103 of the Statute. However, it is emphasized that at this time this is not believed to be the case inasmuch as the Shira Block Declaration only supports what is disclosed in the Gary workbook and does not modify it under section 103.

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18. Claims 5-8, 13-21, 33 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable

over either reference as set forth above and further in view of Viner (6,166,032) or Jones

(6,224,873) or Majeti (5,599,554) or non patent publication to Ferry or Haveson. Goen

Workbook and Gary Method do not appear to teach a stimulant or the specific stimulants recited.

Also although Goen Workbook and Gary Method are considered to teach a weight control

product as recited for example in claim 5, dependent claims reciting only a weight control

product are included in this ground of rejection to the extent it is later determined that the base

references do not teach the weight control product. Each of the secondary references clearly

shows that it is conventional to use a stimulant, and to use the specific stimulants recited in the

claims in combination with an anti-smoking substance taken in a smoking cessation program or

generally as part of a smoking cessation program. Accordingly, it would have been obvious to

one having ordinary skill in the art, in view of any of the noted secondary references, to combine

the apparatus or methods of the base references with the claimed stimulants to make smoking

cessation more effective.

19. Claims 24-27, 29-32, 34-37, 40-43, 45-48 and 50-53 rejected under 35 U.S.C. 103(a) as

being unpatentable over the appropriate references as indicated above and further in view of

Umbdenstock. The references above may not teach all of the recited substances. However

Umbdenstock teaches that it is conventional to take one or more of a number of nutritional

supplements, including well known herbs and other substances such as those claimed, to aid in

the recovery from addiction, including the recovery from addiction to tobacco. Therefore, it

would have been obvious in view of Umbdenstock to provide as part of any smoking cessation

program, including those disclosed in the base references, one or more of the claimed substances,

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to make the program more effective and to help the body recover better from the effects of smoking cessation.

- 20. Claims 28 and 44 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
- 21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob K. Ackun Jr. whose telephone number is (703)308-3867. The examiner can normally be reached on Monday through Friday 8.30AM-5.00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Hail can be reached on (703)308-2687. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob K. Ackun Jr. Primary Examiner Art Unit 3723 Page 10